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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,360	03/16/2001	Eugene M. Wolf	2502440-991501	7725

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/17/2004

258

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,360

Applicant(s)

WOLF, EUGENE M.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-25,27-43 and 50-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-25,27-43 and 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 8, 2003 has been entered as Paper # 23 (Amendment G).

Response to Amendment

2. Applicant's cancellation of claims 56-69 in Paper No. 27 (Amendment G) is acknowledged.
3. With regards to Amendment G (Paper # 27; filed January 07, 2004) the Examiner noticed that claims 44-49 are indicated as being "withdrawn". Examiner respectfully disagrees. As seen in Amendment C (Paper # 12; filed October 8, 2003), these claims were previously cancelled.

Claim Objections

4. Claim 33 is objected to because of the following informality: please add --interior-- after "cancellous" (see line 2). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7, 10, 14, 15, 17, 21, 22, 39, 40, and 51-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a. Regarding claim 7, the limitation “wherein the cancellous region said base extension protrudes into is non-intramedullary” is not further limiting claim 1.
 - b. Regarding claim 10, “the periphery of the partial humeral head fixation” lacks antecedent basis.
 - c. Regarding claim 14, “the periphery of the base of the partial humeral head fixation” lacks antecedent basis.
 - d. Regarding claim 15, “the female template punch” lacks antecedent basis.
 - e. Regarding claim 17, “the periphery of the partial humeral head fixation” lacks antecedent basis.
 - f. Regarding claim 21, “the periphery of the base of the partial humeral head fixation” lacks antecedent basis.
 - g. Regarding claim 22, “the female template punch” lacks antecedent basis.
 - h. Regarding claim 39, “the female template punch” lacks antecedent basis.
 - i. Regarding claim 40, the limitation “to protrude only into a ball region of the humerus above an elongated region of the humerus” is not further limiting claims 25 and/or 31.
 - j. Regarding claim 51, said preparing step (see line 2) renders the claim vague and indefinite since claims 25, 31, or 42-43 present at least two preparing steps. Claims 52 and 53 depend on claim 51.

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k. Regarding claim 53, it is not further limiting claim 51.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3-25, 27-43, and 50-55 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In each of claims 1, 8, 16, 23-25, 31, 42, 43, 50, 54, Applicant positively recites part of a human, i.e., “wherein the base surface of the partial humeral head contacts or substantially mates with the cut humeral surface when coupled therewith”. Thus claims 1, 8, 16, 23-25, 31, 42, 43, 50, 54 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusively property right in a human being is prohibited by the Constitution. In re Wakefield, 422 Fed.Cir.2d 897, 164 USPQ 636 (CCPA 1970).

Examiner respectfully suggests to substitute “wherein the base surface of the partial humeral head contacts or substantially mates with the cut humeral surface when coupled therewith” with --wherein the base surface of the partial humeral head is configured to contact or substantially mate with the cut humeral surface when coupled therewith--.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3-25, 27-43, and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinnet (US 4,550,450 A; cited in Applicant's IDS) in view of Masini (US 5,571,203 A; cited in Applicant's IDS), Swanson et al. (US 4,042,980 A; cited in Applicant's IDS), and Chiron-Werke (DE 1164019; cited in Applicant's IDS).

As seen in Figures 1, 2, 5, and 6, Kinnet discloses a total shoulder arthroplasty apparatus comprising a stemless, partial humeral head fixation (humeral component 10) for coupling to a cut humeral surface (see Figure 1), wherein the partial humeral head fixation includes a partial humeral head (main body portion 20) including a base surface (= root or base wall) and a rotationally-stabilizing (see column 4, lines 40-42) base extension (fixation post/keel 21) protruding therefrom for impaction into a cancellous region of the cut humeral surface (see Figure 1; see entire document). Kinnett also discloses the claimed method of implanting the total shoulder arthroplasty apparatus (see columns 5-7). Kinnett further discloses the use of a template punch (see column 6, lines 40-51). The base extension is impacted and non-intramedullary (see column 7, lines 13-27; see entire document).

Although Kinnett shows the fixation post/keel 21 as having a slight depression (see Figure 1) and also that the fixation post/keel "provides increased mechanical advantages against torque and provides increased surface area of fixation" (see column 4, lines 40-42) and also that

it prevents dislocation (see column 4, lines 50-53), he/she does not particularly disclose the base extension as including a plurality of fins.

a. Masini '203 teaches a prosthetic orthopedic device (see Figures 3-6) comprising a base extension including a plurality of fins (fins 310) in order to limit or prevent the rotational motion of the prosthetic orthopedic device relative to the anchor area/site (see column 4, lines 35-53). Masini also discloses that this plurality of fins (also referred to as anti-rotation means) "may be employed, or used in conjunction with a number of other bone-engaging orthopedic devices to prevent rotation" (see column 4, lines 51-53). Therefore, it would have been obvious to a person of ordinary skill in the art to have combined the teaching of a base extension including a plurality of fins, as taught by Masini, with the prosthetic orthopedic device of Kinnett, in order to limit or prevent the rotational motion of the prosthetic orthopedic device relative to the anchor area/site (i.e., cut humeral surface).

b. Masini '203 teaches several species of anti-rotation means such as: one or more fins, curved fins, posts, and so forth (see column 4, lines 48-53). Masini is evidence of the use of different species of anti-rotation means for a prosthetic orthopedic device. Therefore, it would have been obvious to a person of ordinary skill in the art to have used multiple fins with Kinnett's base extension (= fixation post/keel 21) since, in view of the teachings of Masini, anti-rotation means shaped as one or more fins, curved fins, posts, and so forth, are functionally equal and interchangeable.

Kinnett does not disclose the fixation keel 21 as been linear. However, Swanson et al. and Chiron-Werke teach at least one linear fin extending from the base of the prosthetic orthopedic device in order to anchor the prosthetic orthopedic device and prevent or limit rotational motion

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of it relative to the anchor area/site (see Swanson et al.'s column 3, lines 3-8; see Chiron-Werke entire document). Therefore, it would have been obvious to a person of ordinary skill in the art to have combined the teaching of at least one linear fin extending from the base of the prosthetic orthopedic device, as taught by Swanson et al. and Chiron-Werke, with the prosthetic orthopedic device of Kinnett, in order to anchor the prosthetic orthopedic device and prevent or limit rotational motion of it relative to the anchor area/site (i.e., cut humeral surface).

Response to Arguments

10. Applicant's arguments filed January 7, 2004 have been fully considered but they are not persuasive.

As stated above (see 103(a) rejection), Kinnett discloses the claimed subject matter except for the particular species of anti-rotation means (= multiple fins). From a structural point of view, the particular shape/species of the anchoring aspect/anti-rotation means is what's lacking in Kinnett '450. Masini '203 discloses several species of anti-rotation means for the receptacle shown in his/her Figure 4.

Kinnett not only shows fixation keel 21 in the humeral component 10, but also show a fixation keel 27 in the glenoid component 12. In other words, Kinnett discloses the subject matter of a fixation structure (i.e., keel, rib, fin, etc.) to "provide increased mechanical advantages against torque and provides increased surface area for fixation" (see column 4, lines 40-42) and also that it prevents dislocation (see column 4, lines 50-53). Second, although Masini '203 does not particularly refer to shoulder arthroplasty, he discloses (i) a bone-engaging orthopedic device having a base extension including one or more fins, (ii) the one or more fins

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may include other arrangements (i.e., one or more fins, curved fins, posts, and so forth), (iii) the one or more fins intended use as anti-rotation means (i.e., limit movement of the implant with respect to the bone-engaging surface and prevent rotation), and (iv) the one or more fins “may alternatively be employed, or used in conjunction with a number of other bone-engaging orthopedic devices to prevent rotation”. The combination is deemed proper.

In response to Applicant’s argument that Masini ‘203 is nonanalogous art, it has been held that the determination that a reference is from a nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor’s endeavor. If is not, we proceed to determine whether the reference is reasonably pertinent to the particular invention problem with which the inventor was involved. *In re Wood*, 202 USPQ 171, 174. In this case, the reference is within the same field of endeavor (i.e., bone engaging orthopedic devices). Applicant is also invited to review US 6,056,777 A (cited in PTO-892) wherein the invention pertains to prosthetic shield (= curved trough or cap) used to repair the articulating surfaces of a joint (i.e., hip, shoulder, knee, etc.).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wagner (US 4,035,848), Kleiner (US 4,976,740), Pappas et al. (US 5,702,461), McDowell (US 6,056,777), Rockwood, Jr. et al. (US 6,508,840), Hughes (US 6,589,248), Sullivan et al. (WO 98/07393), and McDevitt et al. (US 2003/0055507).

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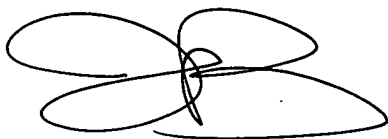
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

March 12, 2004

A handwritten signature consisting of several overlapping loops, likely representing the initials JGB.A handwritten signature in cursive script, likely representing David H. Willse.

David H. Willse
Primary Examiner